REMARKS

Claims 54-85 are pending. The claims are amended to put the application in condition for allowance, and without prejudice to the prosecution of subject matter, canceled by amendment, in other patent applications. The amendments do not constitute new matter.

The claims are rejected under 35 U.S.C. §112. For reasons to be set forth herein, the amended claims have removed the bases for the rejections.

1. The Claims Comply With The Written Description Requirement

Claims 54-85 are rejected under 35 U.S.C. §112 as failing to comply with the written description requirement. According to the Examiner, the term "enhancer" recited in the claims, defined as "a nucleotide sequence that increases the rate of transcription of the therapeutic genes or genes of interest," refers to the *native* enhancer elements associated with expression of naturally occurring human and rat PSGen13 genes. The Examiner contends that the specification does not adequately describe the native enhancer elements of the human or rat PSGen13 genes, because these enhancer elements have not yet been characterized.

Applicants respectfully disagree with the Examiner's interpretation of the specification and claims as necessarily referring to the native enhancers of the human and rat PSGen13 genes. As discussed below, the specification describes the incorporation of the "therapeutic gene," here PSGen13, into vector molecules together with "control elements," which include enhancers. Because heterologous (not native) control elements can affect gene expression, "a nucleotide sequence that increases the rate of transcription of the therapeutic genes or genes of interest" could be a non-native enhancer.

Nevertheless, to put the application in order for allowance, Applicants have amended the claims to refer to PSGen13-encoding sequences operably linked to *promoter* sequences. There is ample support for the use of heterologous promoters for expressing the "therapeutic gene" or "gene of interest," PSGen 13. In particular, Applicants would invite the Examiner's attention to the following text in the instant specification:

> The invention provides for an isolated nucleic acid encoding a Progression Suppressed Gene 13 (PSGen13) protein. . . . The invention provides for a vector comprising the nucleic acid described herein (page 6 lines 12-31);
>
> DNA "control sequences" refers collectively to promoter sequences, polyadenylation signals, transcription termination sequences, upstream regulatory regions, enhancers, and the like, . . . which collectively provide for the transcription and translation of a coding sequence in a host cell. (page 13 lines 31-36);
>
> "Operably linked" refers to an arrangement of nucleotide sequence elements wherein the components so described are configured so as to perform their usual function. Thus, control sequences operably linked to a coding sequence are capable of effecting the expression of the coding sequence. The control sequences need not be contiguous with the coding sequence, so long as they function to direct the expression thereof. Thus, for example, intervening untranslated yet transcribed sequences can be present between a promoter sequence and the coding sequence and the promoter sequence can still be considered "operably linked" to the coding sequence (page 14 lines 1-11);
>
> Construction of suitable vectors containing the desired therapeutic gene coding and control sequences employs standard ligation and restriction techniques, which are well known in the art (page 24 line 36 through page 25 line 3);
>
> A 'heterologous" region of a DNA construct is an identifiable segment of DNA within or attached to another DNA molecule that is not found in association with the other molecule in nature. . . . Likewise, a chimeric sequence, comprising a heterologous structural gene and a gene encoding a PSGen13 or a portion of such gene, linked to a tissue specific promoter, whether derived from the same or a different gene, will be considered heterologous since such chimeric constructs are not normally found in nature. (page 14 line 33 through page 15 line 9); and

> Especially preferred are virus based vectors. . . . Such vectors contain all or a part of the viral genome, such as . . . promoters (e.g., CMV promoters, SV40 promoter, RSV promoter), enhancers, and so forth (page 15 lines 14-18).

The text cited above clearly shows that the specification describes, and that the inventors were in possession of, the invention of a PSGen13-encoding nucleic acid operably linked to a promoter element, which may be a heterologous promoter. Accordingly, the amended claims satisfy the written description requirement, so that this rejection should be withdrawn.

2. The Claims Do Not Contain New Matter

As part of the above rejection under 35 U.S.C. §112 and the written description requirement, the Examiner contends that the specification does not appear to have support for "operatively linking an enhancer element" to an isolated nucleic acid encoding human or rat PSGen13. Applicant is invited by the Examiner to point to supporting language in the specification.

The text cited above (especially page 14 lines 1-11) clearly shows that operatively linking a promoter element to an isolated nucleic acid encoding human or rat PSGen13 is supported by the specification and does not constitute new matter.

Therefore, it is requested that this rejection be withdrawn.

3. The Claims Are Enabled

Claims 54-85 are rejected under 35 U.S.C. § 112, first paragraph, because, according to the Examiner:

> the specification, while being enabling for making an art-known enhancer element, does not reasonably provide enablement for [a] native enhancer element controlling the

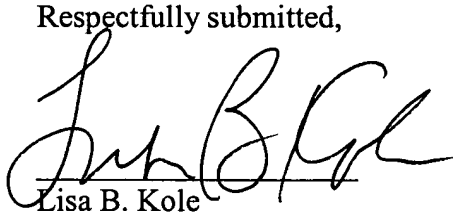
transcription of [a] SEQ ID NO:2 or SEQ ID NO:4 coding region. . . . The base claims 54 and 70 are construed [to] read on an isolated nucleic acid comprising SEQ ID NO: 2 or 4 protein coding region plus [a] native enhancer element controlling the transcription of said coding region. . . . Considering the limited teachings, no working example of an enhancer controlling a human or a rat Suppressed Gene-13 gene transcript encoding SEQ ID NO:2 or 4, unpredictability of art, it is concluded that undue experimentation is required to practice the full scope of the claimed invention.

In response, Applicants assert, as discussed above, that the amended claims, which relate to a promoter operably linked to a nucleic acid encoding PSGen13, are fully supported and enabled by the specification. Therefore, this rejection should be withdrawn.

4. Conclusion

For all the foregoing reasons, the claims meet the requirements for patentability. Therefore, it is respectfully requested that all pending rejections be withdrawn and that the claims be allowed to issue.

Respectfully submitted,



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